

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

REC'D 11 AUG 2005

WIPO

PCT

To:  
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## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY  
(PCT Rule 43bis.1)

Date of mailing (day/month/year) **09. 8. 2005**

Applicant's or agent's file reference  
**P05-41**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.  
**PCT/JP2005/008450**

International filing date (day/month/year)  
**27.04.2005**

Priority date (day/month/year)  
**29.04.2004**

International Patent Classification (IPC) or both national classification and IPC  
**Int.Cl.<sup>7</sup> A61K31/4412, 31/513, 31/53, 45/00, A61P35/00**

Applicant  
**TAIHO PHARMACEUTICAL CO., LTD.**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Date of completion of this opinion

**21. 07. 2005**

Name and mailing address of the ISA/IP

**Japan Patent Office**  
3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan

Authorized officer

**Ikuji Ohtaku**  
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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2005/008450

Box No. I

Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/008450

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1 ~ 28

because:

☒ the said international application, or the said claims Nos. 1 ~ 28

relate to the following subject matter which does not require an international preliminary examination (*specify*):

As claims 1 - 28 are directed to a method for the treatment of human body by therapy, they relate to a subject matter which the International Preliminary Examination Authority is not required, under the Regulations 67.1(iv), to examine.

☐ the description, claims or drawings (indicate particular elements below) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1 ~ 28

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished  
☐ does not comply with the standard

the computer readable form ☐ has not been furnished  
☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions in that the computer readable form:

☐ has not been furnished  
☐ does not comply with the technical requirements

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE  
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PCT/JP2005/008450

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	29-30	NO
Inventive step (IS)	Claims		YES
	Claims	29-30	NO
Industrial applicability (IA)	Claims	29-30	YES
	Claims		NO

2. Citations and explanations

Documents

D1: EP 543015 A1 (TAIHO PHARMACEUTICAL CO., LTD.) 1996.06.11  
D2: Sakata, Y. et. al. Eur J Cancer, Vol.34, No.11, 1998, pp.1715-1720.  
D3: Chollet, P. et. al. Eur J Cancer, Vol.39, No.9, 2003 pp.1264-1270.

Explanation

The subject matter of claims 29 and 30 is not new and does not involve an inventive step because D1, D2 and D3 disclose a pharmaceutical composition comprising tegafur, 2,4-dihydroxy-5-chloropyridine (a dihydropyrimidine dehydrogenase) and oxonic acid.